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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,358	03/12/2004	Peter R. Werp	5236-000420	6341
28997 7590 10/20/2008 HARNESS, DICKEY, & PIERCE, P.L.C 7700 Bonhomme, Suite 400 ST. LOUIS, MO 63105				
EXAMINER				
WEATHERBY, ELLSWORTH				
ART UNIT		PAPER NUMBER		
3768				
MAIL DATE		DELIVERY MODE		
10/20/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/799,358

Applicant(s)

WERP ET AL.

Examiner

ELLSWORTH WEATHERBY

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 8, 10-16, 19-24 and 27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 2, 5, 8, 10-16, 19-24 and 27 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 27 is objected to because of the following informalities: Claim 27 depends from cancelled claim 17. For the purposes of examination the Examiner is interpreting claim 27 to depend from claim 12. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-2, 5, 8, 12-16, 19, 21-22, and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 8 of U.S. Patent No. 7,313,429. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present and the '429

patent claim a magnetic navigation system for orienting a magnetically responsive device in an operating region in a subject using at least two magnet units where the units comprise a positioner for positioning the magnets about a subject where the positioner is controlled such that the selective changes of the magnets maintain a desired magnetic field direction. Although the present application does not expressly claim an imaging system carried on a C arm for imaging the operating region in the subject, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the present application to image the operating region in a subject. The motivation to modify the present application to include a C arm imaging system would have been to visualize the magnetically responsive device within the operating region.

4. Claims 5, 8 and 10-12 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,019,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present application and the '610 patent claim a magnetic navigation system to apply a magnetic field in a selected direction comprising at least two magnets on opposite sides of an operating region and a support for supporting and positioning the magnets about the operating region. The present application does not expressly claim moving the magnet from a state in which the magnet applies a field to the operating region and a second state in which the magnet does not apply a field in the operating region. However, it would have been obvious to

one of ordinary skill in the art at the time of the invention to modify the present application to include positioning the magnets between states in which the magnet does and does not apply a field in the operating region. The motivation to modify the present application to include positioning the magnets between states in which the magnet does and does not apply a field in the operating region would have been to allow an operator to stop or pause the navigation.

5. Claims 1-2, 5, 8 and 19-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-4, 13-14, and 17 of U.S. Patent No. 7,264,584. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the present and the '584 patent teach a magnetic navigation system for orienting a magnetically responsive device in an operating region in a subject using at least two magnet units where the units comprise a positioner for positioning the magnets about a subject where the positioner is controlled such that the selective changes of the magnets maintain a desired magnetic field direction. Also, both the present application and the '584 patent teach avoiding interfering objects and employing models and look up tables to control the movements of the magnets. The present application does not expressly teach a processor or a calculating and transforming step to create sequential field vectors. However, it would have been obvious to one of ordinary skill in the art at the time of the endeavor to have modified the present application to include a processor and a calculating and transforming step to create sequential field vectors. The motivation to

modify the present application to include a processor and a calculating and transforming step to create sequential field vectors would have been to use well known means of magnetically causing translations.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5, 8, 10-16 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani (USPN 4,875,485) in view of Creighton et al. (WO 99/23934).

Matsutani '485 discloses a subject support (col. 3, lines 19-20); two magnet units disposed on opposite sides of an operating region such that they are collinear (figure 1, ref. 19 & 20), each magnet having a magnet positioner and a controller for coordinated movement about an operating region while maintaining a homogeneous support (col. 3, lines 20-44). Matsutani '485 also discloses a support for mounting the at least two magnet units adjacent to the operating region in the subject (col. 4, lines 51-60).

Matsutani '485 does not teach that the magnets are used to orient a magnetically responsive device. Matsutani '485 also does not disclose that two magnet units disposed on opposite sides of an operating region each unit having a positioner for changing the position of the magnet in the unit to change the net direction of the field

while the field is applied. Matsutani '485 also does not expressly teach disposing two magnet units having arcuate supports or stanchions on opposite sides of and operating region. Matsutani '485 also does not disclose that the magnets are rotatable about the operating region in a transverse plane of the subject.

Creighton et al. '934 discloses a controllable pivot for changing the position of the magnet in the unit to change the net direction of the field while the field is applied by the at least two units to orient or navigate a magnetically responsive device (abstract). Creighton et al. '934 also teaches a controlling apparatus may be provided and coupled to articulation systems, the pair of axial coils, the articulation and rotation systems, as well as the imaging system (figure 4, refs. 16,30), as well as control current in a coil used as magnet (pg. 11). Furthermore, Creighton et al. '934 incorporates by reference robotic arm control in response to user input (pg. 9-10).

Creighton et al. '934 also teaches having two magnet units (pg. 4), and wherein the magnet units have an arcuate support arm that permits rotation about the operating region in a transverse plane of the subject where the magnets translate along the plane (figure 3B, ref. 54). Creighton et al. '934 also discloses an imaging system (figure 4, refs. 16,30) comprising a movable support, an imaging beam source (ref. 16), an imaging beam receiver (ref. 28) and a controller for coordinating the movement of the imaging system and the magnets (pg. 4, 9-10).

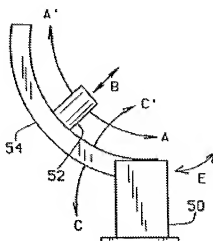


FIG. 3B

Creighton et al. '934 further teaches having two stanchions that are disposed on opposite sides of the patient support, each mounted with identical arcuate support arms, thus permitting rotation about a parallel plane (pg. 4 & 9).

It would have been obvious to modify the movable opposing magnet assembly of Matsutani '485 with the pivoting magnets in the arcuate support arms which are mounted on the two oppositely disposed stanchions as taught by Creighton et al. '934. The motivation to do so would be to supply significant fields in all directions and all locations in an operating region of a patient.

Response to Arguments

8. Applicant's arguments filed 03/20/2008 have been fully considered but they are not persuasive. Regarding applicants arguments with respect to claims 1-2, 5, 8, 10-16, and 27, the Applicant argues that the claims require "a control for operating the positioners of each magnet to selectively change the positions of the magnets to

maintain the magnetic field direction and...". The examiner stands that the control in the reference would be capable of performing that function and that the apparatus must be distinguished from the prior art in terms of structure not function. See MPEP 2114.

Further Regarding applicants arguments with respect to claims 12-16, the Examiner stands that first and second units 50, 52, 54 disposed on opposite sides of a patient of Creighton et al. '934 would inherently retain an opposed relation during an operation (See Creighton et al. '934, Pg. 9).

9. Applicant's arguments, filed 03/20/2008, with respect to the rejection(s) of claim(s) 19-24 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

EW